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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/740,692

12/18/2003

Robert J. Garabedian

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

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DELIVERY MODE

06/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary

Application No.

10/740,692

Applicant(s)

GARABEDIAN ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/05; 3/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 lacks proper antecedent basis for "the distal end of the shaft". There is no structure of a shaft recited in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 8, 9, 11-24, 26, 31, 32 and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoey et al (6,409,722).

Hoey et al disclose an electrosurgical system that includes an RF ablation probe (26 – Figure 1), a source of ablation energy (18) a pump assembly (16 – Figure 2) and a feedback device comprising temperature and/or impedance sensors coupled through a control module (Figure 3) to control the amount of fluid provided to tissue (see Abstract). The disclosure of Hoey et al fully explains the control loops that are used to control both the delivery of RF energy and the flow rate of the fluid based on sensed temperature and impedance, as well as limits for shutting off the energy and/or fluid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 25, 29, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al ('722) in view of the teaching of Imran (5,697,927).

Hoey et al disclose an RF ablation probe and fluid control system as addressed above. Hoey et al, however, fail to show the specifics of the probe. In particular, Hoey et al fail to show a rigid probe or the specific location of the fluid ports on the probe.

Imran discloses another RF ablation device that includes a means to control the flow of a fluid through the probe. In particular, Imran disclose that the probe may be rigid, and also disclose various port configurations including a plurality of side ports on the probe (Figures 7 and 8). Imran also specifically shows the location of the pump assembly in relation to the infusion source as recited in applicant's claim 34. Hoey et al presumably have a similar arrangement, but fail to specifically show the relationship between the pump and the fluid source.

To have provided the Hoey et al device with a rigid RF having a plurality of apertures for the treatment of tissue with RF energy would have been an obvious consideration for one of ordinary skill in the art, particularly since Imran discloses that it is known to use such a probe in a perfused RF procedure with fluid and energy delivery control.

Claims 6, 7, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al ('722) in view of the teaching of Edwards et al (6,613,047).

Again, Hoey et al fail to disclose the specifics of the ablation probe and do not show a needle electrode device for treating tissue.

Edwards et al disclose an RF treatment device that includes a plurality of needle electrodes (Figure 4 and column 4, lines 55+ for the disclosure of multiple needles). Further, the Edwards et al system disclose the control of a fluid flow from the device based on sensed temperature and/or impedance (Figure 17 and associated disclosure).

To have provided the Hoey et al device with an RF probe having one or more needle electrodes for the treatment of tissue with RF energy would have been an obvious consideration for one of ordinary skill in the art, particularly since Edwards et al disclose that it is known to use such a probe in a perfused RF procedure with fluid and energy delivery control.

Claims 10 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (722) in view of the teaching of Mulier et al (7,166,105).

Hoey et al fail to disclose the perfusion source as being located in the handle. Again, Hoey et al simply do not address the specific location of the perfusion source.

Mulier et al disclose yet another fluid controlled RF probe device for delivering a source of fluid to the treatment site via the probe member. In particular, Mulier et al disclose various means for providing the fluid, including external fluid sources or a fluid source located within the handle of the probe (col. 5, lines 30-35).

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To have provided the Hoey et al device with a fluid source located in the handle of the probe for the delivery of a fluid to tissue during an RF procedure would have been an obvious design modification for one of ordinary skill in the art since Mulier et al teach that it is known to locate a perfusion source in the handle of an RF probe.

Allowable Subject Matter

Claim 3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hallock et al (6,285,022), McClurken et al (6,702,810), Nardella (5,334,193) and Webster (6,210,406) all disclose various RF systems that control the flow rate of a fluid to an RF probe during ablation procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner
Art Unit 3739

mp
June 7, 2007